Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

# General

## Guideline Title

Substance use in pregnancy.

## Bibliographic Source(s)

Wong S, Ordean A, Kahan M. Substance use in pregnancy. J Obstet Gynaecol Can. 2011 Apr;33(4):367-84. [161 references] PubMed

## Guideline Status

This is the current release of the guideline.

# Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

# Recommendations

## Major Recommendations

The quality of evidence (I-III) and classification of recommendations (A-L) are defined at the end of the "Major Recommendations."

Identification of Substance-related Disorders in Pregnancy

Screening and Assessment/Role of Toxicology Testing

1. All pregnant women and women of childbearing age should be screened periodically for alcohol, tobacco, and prescription and illicit drug use. (III-A)
2. When testing for substance use is clinically indicated, urine drug screening is the preferred method. (II-2A) Informed consent should be

obtained from the woman before maternal drug toxicology testing is ordered. (III-B)

3. Policies and legal requirements with respect to drug testing of newborns may vary by jurisdiction, and caregivers should be familiar with the regulations in their region. (III-A)

Components of Office Management

4. Health care providers should employ a flexible approach to the care of women who have substance use problems, and they should encourage the use of all available community resources. (II-2B)
5. Women should be counselled about the risks of periconception, antepartum, and postpartum drug use. (III-B)

Nicotine Dependence

Smoking Cessation Counselling/Pharmacotherapy

6. Smoking cessation counselling should be considered as a first-line intervention for pregnant smokers. (I-A) Nicotine replacement therapy and/or pharmacotherapy can be considered if counselling is not successful. (I-A)

Opioid Dependence/Opioids for Chronic Non-Cancer Pain

7. Methadone maintenance treatment should be standard of care for opioid-dependent women during pregnancy. (II-IA) Other slow-release opioid preparations may be considered if methadone is not available. (II-2B)
8. Opioid detoxification should be reserved for selected women because of the high risk of relapse to opioids. (II-2B)
9. Opiate-dependent women should be informed that neonates exposed to heroin, prescription opioids, methadone, or buprenorphine during pregnancy are monitored closely for symptoms and signs of neonatal withdrawal (neonatal abstinence syndrome). (II-2B) Hospitals providing obstetric care should develop a protocol for assessment and management of neonates exposed to opiates during pregnancy. (III-B)

Peripartum Pain Management

10. Antenatal planning for intrapartum and postpartum analgesia may be offered for all women in consultation with appropriate health care providers. (III-B)

Breastfeeding

11. The risks and benefits of breastfeeding should be weighed on an individual basis because methadone maintenance therapy is not a contraindication to breastfeeding. (II-3B)

Definitions:

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action.

B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however,

other factors may influence decision-making.

D. There is fair evidence to recommend against the clinical preventive action.

E. There is good evidence to recommend against the clinical preventive action.

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

†Adapted from the Classification of Recommendations criteria described in The Canadian Task Force on Preventive Health Care.

### Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

- Substance use in pregnancy and lactation
- Substance-related disorders in pregnancy
- Neonatal abstinence syndrome

### Guideline Category

Counseling

Diagnosis

Evaluation

Management

Screening

Treatment

### Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

### Intended Users

Advanced Practice Nurses

Nurses

Physicians

## Guideline Objective(s)

- To improve awareness and knowledge of problematic substance use in pregnancy
- To provide evidence-based recommendations for the management of this challenging clinical issue for all health care providers

## Target Population

- All pregnant women and women of childbearing age (for screening)
- Pregnant women with substance-related disorders
- Substance-using women during the postpartum period, including breastfeeding women
- Neonates exposed to opiates during pregnancy

## Interventions and Practices Considered

1. Screening pregnant women and women of childbearing age for alcohol, tobacco, and prescription and illicit drug use
2. Use of urine for drug screening (hair and meconium are considered, but not recommended for routine testing)
3. Obtaining informed consent before drug screening
4. Provider education on legal requirements with respect to drug testing
5. Use of a flexible approach to the care of women who have substance use problems
6. Counselling women about the risks of periconception, antepartum, and postpartum drug
7. Smoking cessation counselling, nicotine replacement therapy and/or pharmacotherapy for smoking cessation
8. Methadone (or other slow-release opioid preparation) for maintenance treatment for opioid-dependent women during pregnancy
9. Opioid detoxification in select women only
10. Informing women about risk of opiates to neonates
11. Hospital protocol for assessment and management of neonates exposed to opiates during pregnancy
12. Antenatal planning for intrapartum and postpartum analgesia
13. Informing women about risks and benefits of breastfeeding while using substances

## Major Outcomes Considered

- Sensitivity and specificity of drug tests
- Effectiveness of periconception, antepartum, and postpartum drug counselling
- Effectiveness of smoking cessation counselling and interventions
- Effectiveness of methadone maintenance
- Effectiveness of opioid detoxification
- Effects of substance use on maternal, fetal, and neonatal morbidity and mortality

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Medline, PubMed, CINAHL, and The Cochrane Library were searched for articles published from 1950 using the following key words: substance-related disorders, mass screening, pregnancy complications, pregnancy, prenatal care, cocaine, cannabis, methadone, opioid, tobacco, nicotine, solvents, hallucinogens, and amphetamines. Results were initially restricted to systematic reviews and randomized control trials (RCTs)/controlled clinical trials. A subsequent search for observational studies was also conducted because there are few RCTs in this field of study. Articles were restricted to human studies published in English. Additional articles were located by hand searching through article reference lists. Searches were updated on a regular basis and incorporated in the guideline up to December 2009. Grey (unpublished) literature was also identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on the Preventive Health Care. Recommendations for practice were ranked according to the method described in that report.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Not stated

### Rating Scheme for the Strength of the Recommendations

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action.

B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.

D. There is fair evidence to recommend against the clinical preventive action.

E. There is good evidence to recommend against the clinical preventive action.

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

†Adapted from the Classification of Recommendations criteria described in The Canadian Task Force on Preventive Health Care.

### Cost Analysis

- Studies have shown that comprehensive care provided at one site is cost-effective and produces better outcomes for both mother and child.
- Smoking cessation interventions are estimated to be highly cost-effective with savings of US$3 in health-related costs for every US$1 spent on smoking cessation for pregnant women. However, brief interventions are ineffective in preventing postpartum relapse to smoking.

### Method of Guideline Validation

Internal Peer Review

### Description of Method of Guideline Validation

This clinical practice guideline has been prepared by the Working Group on Problematic Substance Use in Pregnancy, reviewed by the Maternal Fetal Medicine Committee, the Family Physicians Advisory Committee, and the Medico-Legal Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- Increased knowledge and comfort level of health care providers caring for pregnant women who have substance use disorders
- Improved access to health care and assistance with appropriate addiction care leads to reduced health care costs and decreased maternal and neonatal morbidity and mortality.

### Potential Harms

- Any regular, daily antenatal opioid exposure (including methadone exposure) can produce neonatal withdrawal, also known as neonatal abstinence syndrome (NAS). Estimates show that up to 96% of infants display withdrawal symptoms, and a smaller proportion require pharmacotherapy. NAS is characterized by respiratory, gastrointestinal, central nervous system, and autonomic symptoms.
- A false positive drug screening result can have serious legal and emotional consequences for the mother.

# Qualifying Statements

## Qualifying Statements

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

## Implementation Tools

Chart Documentation/Checklists/Forms

Foreign Language Translations

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

Safety

# Identifying Information and Availability

## Bibliographic Source(s)

Wong S, Ordean A, Kahan M. Substance use in pregnancy. J Obstet Gynaecol Can. 2011 Apr;33(4):367-84. [161 references] PubMed

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2011 Apr

## Guideline Developer(s)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

## Source(s) of Funding

Society of Obstetricians and Gynaecologists of Canada

## Guideline Committee

Working Group on Problematic Substance Use in Pregnancy

## Composition of Group That Authored the Guideline

*Principal Authors*: Suzanne Wong, MD, Toronto ON; Alice Ordean, MD, Toronto ON; Meldon Kahan, MD, Toronto ON

## Financial Disclosures/Conflicts of Interest

Disclosure statements have been received from all members of the committees.

Dr Alice Ordean received funding from National Institute on Drug Abuse grant R01 DA015741.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site .

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

## Availability of Companion Documents

The appendix of the original guideline document contains an Antenatal Psychosocial Health Assessment (ALPHA) form.

In addition, a French language version of the original guideline document is available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site.

## Patient Resources

None available

## NGC Status

The NGC summary was completed by ECRI Institute on September 28, 2011. The information was verified by the guideline developer on November 2, 2011. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

## Copyright Statement



# Disclaimer

## NGC Disclaimer